

SURVEY OF ACTIVE PHARMACEUTICAL INGREDIENTS EXCIPIENT INCOMPATIBILITY NATURE AND MECHANISM FILE PDF

Survey of Active Pharmaceutical Ingredients-Excipient Incompatibility

To improve physico-chemical properties of an active pharmaceutical ingredient (API) at its preformulation stage, myriad of excipients having defined functional roles like solubility enhancement by co-solvent, micells formation and complexation, intestinal permeability enhancement through the inhibition of efflux transport mechanisms, stability-improvement using pH adjustment, cryo-and lyo-protectants, etc are incorporated into a dosage form containing the API. Although considered primarily as inactive materials, the excipient(s) may react with the API resulting in the development of a detrimental or beneficial substance within the API-loaded dosage form itself. If detrimental substances are formed, then, the issue of API-excipient incompatibility will come up and demand the reformulation of the API, which is costly and time-consuming. This book surveys a comprehensive list of published examples of API-excipient incompatibility relevant to currently or previously marketed drugs. With this coverage, this book also provides first-hand information on the multicomponent nature and complexity of the excipients to the formulation scientist.

Handbook of Pharmaceutical Salts Properties, Selection, and Use

This comprehensive up-to-date guide and information source is an instructive companion for all scientists involved in research and development of drugs and, in particular, of pharmaceutical dosage forms. The editors have taken care to address every conceivable aspect of the preparation of pharmaceutical salts and present the necessary theoretical foundations as well as a wealth of detailed practical experience in the choice of pharmaceutically active salts. Altogether, the contributions reflect the multidisciplinary nature of the science involved in selection of suitable salt forms for new drug products.

Pharmaceutical Excipients

This book provides an overview of excipients, their functionalities in pharmaceutical dosage forms, regulation, and selection for pharmaceutical products formulation. It includes development, characterization methodology, applications, and up-to-date advances through the perspectives of excipients developers, users, and regulatory experts. Covers the sources, characterization, and harmonization of excipients: essential information for optimal excipients selection in pharmaceutical development Describes the physico-chemical properties and biological effects of excipients Discusses chemical classes, safety and toxicity, and formulation Addresses recent efforts in the standardization and harmonization of excipients

Amorphous Solid Dispersions

This volume offers a comprehensive guide on the theory and practice of amorphous solid dispersions (ASD) for handling challenges associated with poorly soluble drugs. In twenty-three inclusive chapters, the book examines thermodynamics and kinetics of the amorphous state and amorphous solid dispersions, ASD technologies, excipients for stabilizing amorphous solid dispersions such as polymers, and ASD

manufacturing technologies, including spray drying, hot melt extrusion, fluid bed layering and solvent-controlled micro-precipitation technology (MBP). Each technology is illustrated by specific case studies. In addition, dedicated sections cover analytical tools and technologies for characterization of amorphous solid dispersions, the prediction of long-term stability, and the development of suitable dissolution methods and regulatory aspects. The book also highlights future technologies on the horizon, such as supercritical fluid processing, mesoporous silica, KinetiSol®, and the use of non-salt-forming organic acids and amino acids for the stabilization of amorphous systems. Amorphous Solid Dispersions: Theory and Practice is a valuable reference to pharmaceutical scientists interested in developing bioavailable and therapeutically effective formulations of poorly soluble molecules in order to advance these technologies and develop better medicines for the future.

Excipient Applications in Formulation Design and Drug Delivery

In recent years, emerging trends in the design and development of drug products have indicated ever greater need for integrated characterization of excipients and in-depth understanding of their roles in drug delivery applications. This book presents a concise summary of relevant scientific and mechanistic information that can aid the use of excipients in formulation design and drug delivery applications. Each chapter is contributed by chosen experts in their respective fields, which affords truly in-depth perspective into a spectrum of excipient-focused topics. This book captures current subjects of interest – with the most up to date research updates – in the field of pharmaceutical excipients. This includes areas of interest to the biopharmaceutical industry users, students, educators, excipient manufacturers, and regulatory bodies alike.

Handbook of Pharmaceutical Excipients

An internationally acclaimed reference work recognized as one of the most authoritative and comprehensive sources of information on excipients used in pharmaceutical formulation with this new edition providing 340 excipient monographs. Incorporates information on the uses, and chemical and physical properties of excipients systematically collated from a variety of international sources including: pharmacopeias, patents, primary and secondary literature, websites, and manufacturers' data; extensive data provided on the applications, licensing, and safety of excipients; comprehensively cross-referenced and indexed, with many additional excipients described as related substances and an international supplier's directory and detailed information on trade names and specific grades or types of excipients commercially available.

Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems

To facilitate the development of novel drug delivery systems and biotechnology-oriented drugs, the need for new excipients to be developed and approved continues to increase. Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems serves as a comprehensive source to improve understanding of excipients and forge new avenue

Developing Solid Oral Dosage Forms

Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and

regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

Dosage Form Design Parameters

Dosage Form Design Parameters, Volume II, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries. Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, preformulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates, graduate students and those interested in drug dosage design

Basic Fundamentals of Drug Delivery

Basic Fundamentals of Drug Delivery covers the fundamental principles, advanced methodologies and technologies employed by pharmaceutical scientists, researchers and pharmaceutical industries to transform a drug candidate or new chemical entity into a final administrable drug delivery system. The book also covers various approaches involved in optimizing the therapeutic performance of a biomolecule while designing its appropriate advanced formulation. Provides up-to-date information on translating the physicochemical properties of drugs into drug delivery systems Explores how drugs are administered via various routes, such as orally, parenterally, transdermally or through inhalation Contains extensive references and further reading for course and self-study

Handbook of Pharmaceutical Wet Granulation

Handbook of Pharmaceutical Wet Granulation: Theory and Practice in a Quality by Design Paradigm offers a single and comprehensive reference dedicated to all aspects of pharmaceutical wet granulation, taking a holistic approach by combining introductory principles with practical solutions. Chapters are written by international experts across industry, academic and regulatory settings, and cover a wide spectrum of relevant and contemporary wet granulation topics, techniques and processes. The books' focus on process analytical technology, quality by design principles, granulation equipment, modeling, scale-up, control and real time release makes it a timely and valuable resource for all those involved in pharmaceutical wet granulation. Discusses fundamentals of theory and current industrial practice in the field of wet granulation, including product and process design and role of material properties in wet granulation Examines the modern evolution of wet granulation through current topics such as established and novel process analytical technologies (PATs), and product development and scale-up paradigms Written for scientists working within the pharmaceutical industry, as well as academics, regulatory officials and equipment vendors who provide PAT tools and granulation equipment

Pharmaceutical Formulation Design

Pharmaceutical formulations have evolved from simple and traditional systems to more modern and complex novel dosage forms. Formulation development is a tedious process and requires an enormous amount of effort from many different people. Developing a stable novel dosage form and further targeting it to the desired site inside the body has always been a challenge. The purpose of this book is to bring together scholarly articles that highlight recent developments and trends in pharmaceutical formulation science. Each article has been written by authors specializing in the subject area and hailing from top institutions around the world. The book has been written in a systematic and lucid style explaining all basic concepts and fundamentals in a very simple way. This book aims to serve the need of all individuals involved at any level in the pharmaceutical dosage form development. I sincerely hope that the book will be liked by inquisitive students and learned colleagues.

Peptide Therapeutics

Peptide therapy has become a key strategy in innovative drug development, however, one of the potential barriers for the development of novel peptide drugs in the clinic is their deficiencies in clearly defined chemistry, manufacturing and controls (CMC) strategy from clinical development to commercialization. CMC can often become a rate-limiting step due to lack of knowledge and lack of a formal policy or guidelines on CMC for peptide-based drugs. Regulators use a risk-based approach, reviewing applications on a case-by-case basis. *Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing, and Controls* covers efficient manufacturing of peptide drug substances, a review of the process for submitting applications to the regulatory authority for drug approval, a holistic approach for quality attributes and quality control from a regulatory perspective, emerging analytical tools for the characterisation of impurities, and the assessment of stability. This book is an essential reference work for students and researchers, in both academia and industry, with an interest in learning about CMC, and facilitating development and manufacture of peptide-based drugs.

Pharmaceutical Dosage Forms

Quality management (QM) practices are the basis for the successful implementation and maintenance of any QM system. Quality control (QC) is identified as a QM component. Therefore, QM effectiveness is dependent on the QC strategy. QC practice is more or less complex depending on the type of production. The book is focused on new trends and developments in QM and QC in several types of industries from a worldwide perspective. Its content has been organized into two sections and seven chapters written by well-recognized researchers worldwide. Several approaches are debated based on sample traceability, analytical method validation, required parameters, class of exponential regression-type estimators of the population means, determination of impurities, viewpoints, and case studies.

Quality Management and Quality Control

Metered Dose Inhaler Technology explores the technologies of pressurized metered dose inhalation (MDI) delivery systems and provides practical, easy-to-use guidance to effective product formulation. With contributions from an international panel of authors, the book addresses the global phase-out of chlorofluorocarbon chemicals (CFCs), the generation of propellant systems to replace them, and their associated new medications and therapies. Topics include the manufacture of metered dose inhalers, particle size analysis in inhalation therapy, development and testing, pharmacokinetics and metabolism of propellants, toxicology, and more.

Metered Dose Inhaler Technology

Oral Drug Absorption, Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally. The contributors discuss methods for accurately establishing and validating in vitro/in vivo correlations for both MR and IR formulations, as well

as alternative approaches for MR an

Oral Drug Absorption

Until the 1990s, it was generally accepted that medicines were first developed for adults and their use in children was investigated later, if at all. One of the main tasks of hospital pharmacies was the manufacturing of child-appropriate formulations in a more or less makeshift way. The first change came in 1997 with U.S. legislation that rewarded manufacturers to do voluntary pediatric research. Ten years later, the European Union passed legislation that required manufacturers to discuss all pediatric aspects, including formulations, with the regulatory authorities as a condition of starting the registration procedure. In consequence, manufacturers must now cover all age groups, including the youngest ones. So far, pediatric formulations were more a focus for academic researchers. Through the changed regulatory environment, there is now a sudden high commercial demand for age-appropriate formulations. This book begins by highlighting the anatomical, physiological and developmental differences between adults and children of different ages. It goes on to review the existing technologies and attempts to draw a roadmap to better, innovative formulations, in particular for oral administration. The regulatory, clinical, ethical and pharmaceutical framework is also addressed.

Pediatric Formulations

Pain is both a symptom and a disease. It manifests in multiple forms and its treatment is complex. Physical, social, economic, and emotional consequences of pain can impair an individual's overall health, well-being, productivity, and relationships in myriad ways. The impact of pain at a population level is vast and, while estimates differ, the Centers for Disease Control and Prevention reported that 50 million U.S. adults are living in pain. In terms of pain's global impact, estimates suggest the problem affects approximately 1 in 5 adults across the world, with nearly 1 in 10 adults newly diagnosed with chronic pain each year. In recent years, the issues surrounding the complexity of pain management have contributed to increased demand for alternative strategies for treating pain. One such strategy is to expand use of topical pain medications—medications applied to intact skin. This nonoral route of administration for pain medication has the potential benefit, in theory, of local activity and fewer systemic side effects. Compounding is an age-old pharmaceutical practice of combining, mixing, or adjusting ingredients to create a tailored medication to meet the needs of a patient. The aim of compounding, historically, has been to provide patients with access to therapeutic alternatives that are safe and effective, especially for people with clinical needs that cannot otherwise be met by commercially available FDA-approved drugs. *Compounded Topical Pain Creams* explores issues regarding the safety and effectiveness of the ingredients in these pain creams. This report analyzes the available scientific data relating to the ingredients used in compounded topical pain creams and offers recommendations regarding the treatment of patients.

Compounded Topical Pain Creams

This is thirty-fifth edition of Martindale, which provides reliable, and evaluated information on drugs and medicines used throughout the world. It contains encyclopaedic facts about drugs and medicines, with: 5,500 drug monographs; 128,000 preparations; 40,700 reference citations; 10,900 manufacturers. There are synopses of disease treatments which enables identification of medicines, the local equivalent and the manufacturer. It also Includes herbals, diagnostic agents, radiopharmaceuticals, pharmaceutical excipients, toxins, and poisons as well as drugs and medicines. Based on published information and extensively referenced

Martindale

Pharmaceutical Medicine and Translational Clinical Research covers clinical testing of medicines and the translation of pharmaceutical drug research into new medicines, also focusing on the need to understand the

safety profile of medicine and the benefit-risk balance. Pharmacoeconomics and the social impact of healthcare on patients and public health are also featured. It is written in a clear and straightforward manner to enable rapid review and assimilation of complex information and contains reader-friendly features. As a greater understanding of these aspects is critical for students in the areas of pharmaceutical medicine, clinical research, pharmacology and pharmacy, as well as professionals working in the pharmaceutical industry, this book is an ideal resource. Includes detailed coverage of current trends and key topics in pharmaceutical medicine, including biosimilars, biobetters, super generics, and Provides a comprehensive look at current and important aspects of the science and regulation of drug and biologics discovery

Pharmaceutical Medicine and Translational Clinical Research

This study has emerged from an ongoing program of trilateral cooperation between WHO, WTO and WIPO. It responds to an increasing demand, particularly in developing countries, for strengthened capacity for informed policy-making in areas of intersection between health, trade and IP, focusing on access to and innovation of medicines and other medical technologies.

Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade

Advances and Avenues in the Development of Novel Carriers for Bioactives and Biological Agents provides sound data on the utility of biological and plant-based drugs and describes challenges faced in all aspects offering indispensable strategies to use in the development of bioactive medicines. Bioactive based medications are commonly used throughout the world and have been recognized by physicians and patients for their therapeutic efficacy. Bioactive formulations, including their subordinates and analogs, address 50% of all medicines in clinical practice. Novel bioactive medicine transporters can cure many disorders by both spatial and transitory approaches and have various justifications in medicinal potential. This book presents information on the utility of natural, plant, animal and bioengineered bioactive materials. It is a fundamental source of information and data for pharmacognosists, pharmaceutical analysts, drug transport scientists and pharmacologists working in bioactive medications. Advances information on various bioactive based medications, their sources, clinical consequences and transport strategies Illustrates diverse transport systems for bioactives and derivatives, novel techniques for formulations, targeting strategies and fundamental qualities of developed bioactive carriers, and their safety concerns and standardization Discusses distinctive transport systems, stability, upgraded dissolvability, and enhanced bioavailability of bioactives

Advances and Avenues in the Development of Novel Carriers for Bioactives and Biological Agents

Hot-melt extrusion (HME) - melting a substance and forcing it through an orifice under controlled conditions to form a new material - is an emerging processing technology in the pharmaceutical industry for the preparation of various dosage forms and drug delivery systems, for example granules and sustained release tablets. Hot-Melt Extrusion: Pharmaceutical Applications covers the main instrumentation, operation principles and theoretical background of HME. It then focuses on HME drug delivery systems, dosage forms and clinical studies (including pharmacokinetics and bioavailability) of HME products. Finally, the book includes some recent and novel HME applications, scale -up considerations and regulatory issues. Topics covered include: principles and die design of single screw extrusion twin screw extrusion techniques and practices in the laboratory and on production scale HME developments for the pharmaceutical industry solubility parameters for prediction of drug/polymer miscibility in HME formulations the influence of plasticizers in HME applications of polymethacrylate polymers in HME HME of ethylcellulose, hypromellose, and polyethylene oxide bioadhesion properties of polymeric films produced by HME taste masking using HME clinical studies, bioavailability and pharmacokinetics of HME products injection moulding and HME processing for pharmaceutical materials laminar dispersive & distributive mixing with

dissolution and applications to HME technological considerations related to scale-up of HME processes devices and implant systems by HME an FDA perspective on HME product and process understanding improved process understanding and control of an HME process with near-infrared spectroscopy Hot-Melt Extrusion: Pharmaceutical Applications is an essential multidisciplinary guide to the emerging pharmaceutical uses of this processing technology for researchers in academia and industry working in drug formulation and delivery, pharmaceutical engineering and processing, and polymers and materials science. This is the first book from our brand new series Advances in Pharmaceutical Technology. Find out more about the series [here](#).

Hot-Melt Extrusion

This textbook is written as a unified approach to various topics, ranging from drug discovery to manufacturing, techniques and technology, regulation and marketing. The key theme of the book is pharmaceuticals - what every student of pharmaceutical sciences should know: from the active pharmaceutical ingredients to the preparation of various dosage forms along with the relevant chemistry, this book makes pharmaceuticals relevant to undergraduate students of pharmacy and pharmaceutical sciences. This book explains how a particular drug was discovered and then converted from lab-scale to manufacturing scale, to the market. It explains the motivation for drug discovery, the reaction chemistry involved, experimental difficulties, various dosage forms and the reasoning behind them, mechanism of action, quality assurance and role of regulatory agencies. After having a course based on this book, the student will be able to understand: 1) the career prospects in the pharmaceutical industry, 2) the need for interdisciplinary teamwork in science, 3) the techniques and technology involved in making pharmaceuticals starting from bulk drugs, and 4) different dosage forms and critical factors in the development of pharmaceutical formulations in relation to the principles of chemistry. A few blockbuster drugs including atorvastatin, sildanefil, ranitidine, ciprofloxacin, amoxicillin, and the longest serving drugs such as aspirin and paracetamol are discussed in detail. Finally, the book also covers the important current pharmaceutical issues like quality control, safety, counterfeiting and abuse of drugs, and future prospects for pharmaceutical industry. Unified approach explaining drug discovery, bulk drug manufacturing, formulation of dosage forms, with pharmacological and therapeutic actions Manufacturing processes of representative active pharmaceutical ingredients and their chemistry plus formulation of dosage forms presented in this book are based on actual industrial processes Covers many aspects relevant to students of the pharmaceutical sciences or newly employed pharmaceutical researchers/employees. It contains summary information about regulatory agencies of different countries

An Introduction to Pharmaceutical Sciences

Easy Statistics for Food Science with R presents the application of statistical techniques to assist students and researchers who work in food science and food engineering in choosing the appropriate statistical technique. The book focuses on the use of univariate and multivariate statistical methods in the field of food science. The techniques are presented in a simplified form without relying on complex mathematical proofs. This book was written to help researchers from different fields to analyze their data and make valid decisions. The development of modern statistical packages makes the analysis of data easier than before. The book focuses on the application of statistics and correct methods for the analysis and interpretation of data. R statistical software is used throughout the book to analyze the data. Contains numerous step-by-step tutorials help the reader to learn quickly Covers the theory and application of the statistical techniques Shows how to analyze data using R software Provides R scripts for all examples and figures

Easy Statistics for Food Science with R

NMR spectroscopy is the most valuable and versatile analytical tool in chemistry. While excellent monographs exist on high-resolution NMR in liquids and solids, this is the first book to address multidimensional solid-state NMR. Multidimensional techniques enable researchers to obtain detailed

information about the structure, dynamics, orientation, and phase separation of solids, which provides the basis of a better understanding of materials properties on the molecular level. Dramatic progress-much of it pioneered by the authors-has been achieved in this area, especially in synthetic polymers. Solid-state NMR now favorably competes with well-established techniques, such as light, x-ray, or neutron scattering, electron microscopy, and dielectric and mechanical relaxation. The application of multidimensional solid-state NMR inevitably involves use of concepts from different fields of science. This book also provides the first comprehensive treatment of both the new experimental techniques and the theoretical concepts needed in more complex data analysis. The text addresses spectroscopists and polymer scientists by treating the subject on different levels; descriptive, technical, and mathematical approaches are used when appropriate. It presents an overview of new developments with numerous experimental examples and illustrations, which will appeal to readers interested in both the information content as well as the potential of solid-state NMR. The book also contains many previously unpublished details that will be appreciated by those who want to perform the experiments. The techniques described are applicable not only to the study of synthetic polymers but to numerous problems in solid-state physics, chemistry, materials science, and biophysics. Key Features

- * Presents original theories and new perspectives on scattering techniques
- * Provides a systematic treatment of the whole subject
- * Gives readers access to previously unpublished material
- * Includes extensive illustrations

Multidimensional Solid-State NMR and Polymers

Formulation, Development and Manufacturing of Vaccines: The Practical Aspects provides an industry perspective on vaccine product development and manufacture that covers their formulation development, manufacture and delivery/in-use considerations of vaccine production. With the increasing complexity of vaccine products in development, there is a need for a comprehensive review of the current state of the industry and its challenges. While formulation scientists working in biotherapeutic development may be familiar with proteins, vaccines present unique challenges, including the wide range of vaccine components that may comprise proteins, polysaccharides, protein-polysaccharide conjugates, adjuvants, etc. and the varying stability and behavior of solution- and suspension-based systems. This book is an essential resource for formulation scientists, researchers in vaccine development throughout medical and life sciences, and advanced students. Includes formulation considerations for various vaccine types, including proteins, polysaccharides, conjugates and live vaccines Considers process development for solution, suspension and lyophilized products Explores the future potential of vaccines, including multi-component vaccines and novel delivery mechanisms/devices

Practical Aspects of Vaccine Development

Handbook of Modern Pharmaceutical Analysis, Second Edition, synthesizes the complex research and recent changes in the field, while covering the techniques and technology required for today's laboratories. The work integrates strategy, case studies, methodologies, and implications of new regulatory structures, providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis (PA) as an integral partner to the drug development process rather than as a service to it Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations Features detailed coverage of QA, ethics, and regulatory guidance (quality by design, good manufacturing practice), as well as high-tech methodologies and technologies from "lab-on-a-chip" to LC-MS, LC-NMR, and LC-NMR-MS

Handbook of Modern Pharmaceutical Analysis

Inorganic Controlled Release Technology: Materials and Concepts for Advanced Drug Formulation provides a practical guide to the use and applications of inorganic controlled release technology (iCRT) for drug delivery and other healthcare applications, focusing on newly developed inorganic materials such as bioresorbable glasses and bioceramics. The use of these materials is introduced for a wide range of

applications that cover inorganic drug delivery systems for new drug development and the reformulation of existing drugs. The book describes basic concepts, principles, and industrial practices by discussing materials chemistry, physics, nano/microstructure, formulation, materials processing, and case studies, as well as the evaluation and characterization of iCRT systems commonly investigated during industrial R&D. Provides the first book on inorganic controlled release technology (iCRT), covering key aspects from chemistry, physics, synthetic methods, formulation design, characterization and evaluation. Includes several industry-related case studies to provide practical guidance on how to use iCRT as an alternative to organic polymers systems for both future drug developments and other active ingredient applications. Demonstrates how iCRT offers an unmet business need for improved, controlled release of actives versus traditional CRT systems, which are known to have difficulty with the controlled delivery of both poorly and highly water soluble drug compounds.

Inorganic Controlled Release Technology

Multi-component crystalline systems or co-crystals have received tremendous attention from academia and industry alike in the past decade. Applications of co-crystals are varied and are likely to positively impact a wide range of industries dealing with molecular solids. Co-crystallization has been used to improve the properties and performance of materials from pharmaceuticals to energetic materials, as well as for separation of compounds. This book combines co-crystal applications of commercial and practical interest from diverse fields in to a single volume. It also examines effective structural design of co-crystals, and provides insights into practical synthesis and characterization techniques. Providing a useful resource for postgraduate students new to applied co-crystal research and crystal engineering, it will also be of interest to established researchers in academia or industry.

Co-crystals

3D printing is forecast to revolutionise the pharmaceutical sector, changing the face of medicine development, manufacture and use. Potential applications range from pre-clinical drug development and dosage form design through to the fabrication of functionalised implants and regenerative medicine. Within clinical pharmacy practice, printing technologies may finally lead to the concept of personalised medicines becoming a reality. This volume aims to be the definitive resource for anyone thinking of developing or using 3D printing technologies in the pharmaceutical sector, with a strong focus on the translation of printing technologies to a clinical setting. This text brings together leading experts to provide extensive information on an array of 3D printing techniques, reviewing the current printing technologies in the pharmaceutical manufacturing supply chain, in particular, highlighting the state-of-the-art applications in medicine and discussing modern drug product manufacture from a regulatory perspective. This book is a highly valuable resource for a range of demographics, including academic researchers and the pharmaceutical industry, providing a comprehensive inventory detailing the current and future applications of 3D printing in pharmaceuticals. Abdul W. Basit is Professor of Pharmaceutics at the UCL School of Pharmacy, University College London. Abdul's research sits at the interface between pharmaceutical science and gastroenterology, forging links between basic science and clinical outcomes. He leads a large and multidisciplinary research group, and the goal of his work is to further the understanding of gastrointestinal physiology by fundamental research. So far, this knowledge has been translated into the design of new technologies and improved disease treatments, many of which are currently in late-stage clinical trials. He has published over 350 papers, book chapters and abstracts and delivered more than 250 invited research presentations. Abdul is also a serial entrepreneur and has filed 25 patents and founded 3 pharmaceutical companies (Kuecept, Intract Pharma, FabRx). Abdul is a frequent speaker at international conferences, serves as a consultant to many pharmaceutical companies and is on the advisory boards of scientific journals, healthcare organisations and charitable bodies. He is the European Editor of the International Journal of Pharmaceutics. Abdul was the recipient of the Young Investigator Award in Pharmaceutics and Pharmaceutical Technology from the American Association of Pharmaceutical Scientists (AAPS) and is the only non-North American scientist to receive this award. He was also the recipient of the Academy of Pharmaceutical Sciences (APS) award.

Simon Gaisford holds a Chair in Pharmaceutics and is Head of the Department of Pharmaceutics at the UCL School of Pharmacy, University College London. He has published 110 papers, 8 book chapters and 4 authored books. His research is focused on novel technologies for manufacturing medicines, particularly using ink-jet printing and 3D printing, and he is an expert in the physico-chemical characterisation of compounds and formulations with thermal methods and calorimetry.

3D Printing of Pharmaceuticals

Accelerated Predictive Stability (APS): Fundamentals and Pharmaceutical Industry Practices provides coverage of both the fundamental principles and pharmaceutical industry applications of the APS approach. Fundamental chapters explain the scientific basis of the APS approach, while case study chapters from many innovative pharmaceutical companies provide a thorough overview of the current status of APS applications in the pharmaceutical industry. In addition, up-to-date experiences in utilizing APS data for regulatory submissions in many regions and countries highlight the potential of APS in support of registration stability testing for certain regulatory submissions. This book provides high level strategies for the successful implementation of APS in a pharmaceutical company. It offers scientists and regulators a comprehensive resource on how the pharmaceutical industry can enhance their understanding of a product's stability and predict drug expiry more accurately and quickly. Provides a comprehensive, one-stop-shop resource for accelerated predictive stability (APS) Presents the scientific basis of different APS models Includes the applications and utilities of APS that are demonstrated through numerous case studies Covers up-to-date regulatory experience

Accelerated Predictive Stability (APS)

The third volume in the six-volume Handbook of Pharmaceutical Manufacturing Formulations, this book covers liquid drugs, which include formulations of non-sterile drugs administered by any route in the form of solutions (monomeric and multimeric), suspensions (powder and liquid), drops, extracts, elixirs, tinctures, paints, sprays, colloids, emulsions

Handbook of Pharmaceutical Manufacturing Formulations

This third edition expands on the previous editions with updated and new chapters on protein chromatography. Chapters detail protein stability and storage, avoiding proteolysis, protein quantitation methods, generation and purification of recombinant proteins, recombinant antibody production, and the tagging of proteins. Written in the format of the highly successful Methods in Molecular Biology series, each chapter includes an introduction to the topic, lists necessary materials and reagents, includes tips on troubleshooting and known pitfalls, and step-by-step, readily reproducible protocols. Authoritative and cutting-edge, Protein Chromatography: Methods and Protocols, Third Edition aims to provide commonly used methods and new approaches to help both new researchers and experts expand their knowledge.

Protein Chromatography

Alginates in Drug Delivery explores the vital precepts, basic and fundamental aspects of alginates in pharmaceutical sciences, biopharmacology, and in the biotechnology industry. The use of natural polymers in healthcare applications over synthetic polymers is becoming more prevalent due to natural polymers' biocompatibility, biodegradability, economic extraction and ready availability. To fully utilize and harness the potential of alginates, this book presents a thorough understanding of the synthesis, purification, and characterization of alginates and their derivative. This book collects, in a single volume, all relevant information on alginates in health care, including recent advances in the field. This is a highly useful resource for pharmaceutical scientists, health care professionals and regulatory scientists actively involved in the pharmaceutical product and process development of natural polymer containing drug delivery, as well as postgraduate students and postdoctoral research fellows in pharmaceutical sciences. Provides a single source

on the complete alginate chemistry, collection, chemical modifications, characterization and applications in healthcare fields Includes high quality illustrations, along with practical examples and research case studies Contains contributions by global leaders and experts from academia, industry and regulatory agencies who are pioneers in the application of natural polysaccharides in diverse pharmaceutical fields

Alginates in Drug Delivery

Dosage Form Design Parameters, Volume I, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries. Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, preformulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates, graduate students and those interested in drug dosage design

Dosage Form Design Considerations

This book describes the theories, applications, and challenges for different oral controlled release formulations. This book differs from most in its focus on oral controlled release formulation design and process development. It also covers the related areas like preformulation, biopharmaceutics, in vitro-in vivo correlations (IVIVC), quality by design (QbD), and regulatory issues.

Oral Controlled Release Formulation Design and Drug Delivery

Providing a roadmap from early to late stages of drug development, this book overviews amorphous solid dispersion technology – a leading platform to deliver poorly water soluble drugs, a major hurdle in today's pharmaceutical industry. • Helps readers understand amorphous solid dispersions and apply techniques to particular pharmaceutical systems • Covers physical and chemical properties, screening, scale-up, formulation, drug product manufacture, intellectual property, and regulatory considerations • Has an appendix with structure and property information for polymers commonly used in drug development and with marketed drugs developed using the amorphous solid dispersion approach • Addresses global regulatory issues including USA regulations, ICH guidelines, and patent concerns around the world

Pharmaceutical Amorphous Solid Dispersions

HPLC for Pharmaceutical Scientists is an excellent book for both novice and experienced pharmaceutical chemists who regularly use HPLC as an analytical tool to solve challenging problems in the pharmaceutical industry. It provides a unified approach to HPLC with an equal and balanced treatment of the theory and practice of HPLC in the pharmaceutical industry. In-depth discussion of retention processes, modern HPLC separation theory, properties of stationary phases and columns are well blended with the practical aspects of fast and effective method development and method validation. Practical and pragmatic approaches and actual examples of effective development of selective and rugged HPLC methods from a physico-chemical point of view are provided. This book elucidates the role of HPLC throughout the entire drug development process from drug candidate inception to marketed drug product and gives detailed specifics of HPLC application in each stage of drug development. The latest advancements and trends in hyphenated and specialized HPLC techniques (LC-MS, LC-NMR, Preparative HPLC, High temperature HPLC, high pressure liquid chromatography) are also discussed.

HPLC for Pharmaceutical Scientists

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